

Comprehensive Genomic & Transcriptomic Profiling with High-sensitive ctDNA-MRD Monitoring

● Informed Decision-Making with Comprehensive Profiling

DNA

Genomic profiling of 515 genes with backbone-enhanced design and sWGS

Covers all biomarkers for treatment selection, diagnosis & prognosis

Boosts accuracy in detecting rare large indels and structural variants

RNA

Transcriptomic profiling (mRNA-seq) of 19,435 genes

20% increase in sensitivity for detecting both common and rare fusion variants ⁽¹⁾

High accuracy machine-learning model for tumor tissue-of-origin prediction ⁽¹⁾

Tumor-Normal Analysis

Tumor and white blood cell pairing; reduces false positives compared to tumor-only testing

● Insightful Monitoring with High-sensitive ctDNA-MRD Results

ctDNA-MRD
LOD = 0.005%

ctDNA-MRD monitoring tracks tumor evolution and emerging actionable or resistance mutations



Tracking
Profile

Up to 50 tumor-derived mutations + 113 – 149 tumor-agnostic genes (panel depending on the cancer type)



Viral DNA

Enhances tracking for virus-related cancers



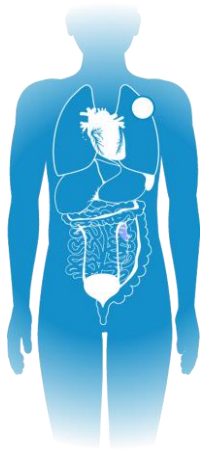
AI-enhanced

Integrates non-mutation genome-wide features of ctDNA

Methodology

A K-4CARE 1st | Treatment Selection

TAT – 8 working days*



Tumor Profiling
Genomic & Transcriptomic Profiling

All solid tumors
Blood cancers
Cancer of Unknown Primary (CUP)

Targeted Therapy
Actionable & resistance mutations
Homologous recombination deficiency (HRD)

Immunotherapy
Microsatellite Instability (MSI)
Tumor Mutational Burden (TMB)
Programmed Death Ligand 1 (PD-L1) (optional)

Prognosis/Diagnosis Biomarkers
Oncoviruses
Chromosomes
Biomarkers with unknown significance

Cancer of Unknown Primary (CUP)
Tumor Tissue of Origin (TOO)



Personalized
profiling

Mutations

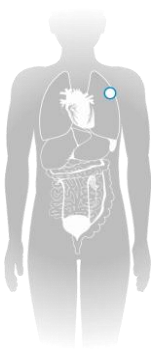
Up to 50 tumor-derived mutations + 113-149-gene panels (panel depending on the cancer type)

Viral DNA
EBV, HPV

Genome-wide features
Non-mutation features
(CNA, Fragmentomics ...)

B K-4CARE 1st | Baseline ctDNA Assessment

TAT – 8 working days**



ctDNA baseline status

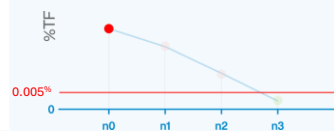
Limit of Detection (LOD): 0.005%



Pre-treatment:
Establish baseline ctDNA level
Detect tumor-agnostic mutations
Germline mutations (pharmacogenomics – DPYD and hereditary cancer risk assessment)

+ **Positive result**
Higher pre-treatment ctDNA results correlates with shorter overall survival (OS) and progression-free survival (PFS).

- **Negative result**
Associated with favorable prognosis, aiding risk stratification.

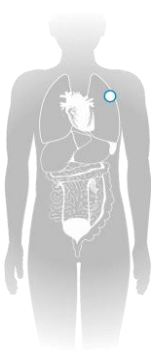


Note: ctDNA detection rate depends on tumor volume, growth rate, location, and shedding rate.

Personalized tracking profile

C K-4CARE (n) | Treatment Monitoring

TAT – 8 working days***



ctDNA monitoring

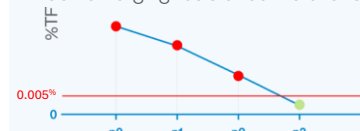
Limit of Detection (LOD): 0.005%



Post-treatment:
Analyze ctDNA dynamics to assess treatment response
Detect tumor-agnostic mutations
Track emerging resistance mutations

+ **Positive result**
(Lack of ctDNA clearance)
Predicts non-response or partial response to treatment; associated with higher risk of disease progression.

- **Negative result**
(ctDNA clearance)
Predicts favorable treatment response.



Note: ctDNA detection rate depends on tumor volume, growth rate, location, and shedding rate.

Analytical Performance of Tumor & Blood Biopsy Profiling



Analytical performance for
tumor FFPE sample

		Minimum tumor fraction	Sensitivity ^a	Specificity ^a	Positivity threshold
Targeted therapy (FFPE)	DNA-based somatic variant detection (at LOD = 5%) ^b				
	SNVs	20%	>99%	>99%	≥5% VAF
	INDELs	20%	>99%	>99%	
	Amplification	20%	>99%	>99%	≥2 copy ratio
	Fusion (common fusions)	20%	94%	>99%	≥2 reads at breakpoint
	RNA-based somatic variant detection				
	Fusion (all genes)	20%	>99%	>99%	≥5 reads
Hereditary cancer (WBC)	MET ex14 skipping	20%	>99%	>99%	≥10 reads
	Germline variants				
	SNVs		>99%	>99%	
HRD status (FFPE)	INDELs		>99%	>99%	
	Genomic instability	30%	OPA ^c = 96.3%		wGI ≥ 0
	BRCA1/2 mutations	20%	>99%	>99%	≥5% VAF
Immunotherapy ^d (FFPE)	MSI	20%	94%	>99%	≥20%
	TMB	20%	R ² correlation: 97%		≥10 muts/Mb
Tissue of origin ^e (FFPE)	Primary tumor	20%	Accuracy: 87.7%		
	Metastatic tumor	20%	Accuracy: 81.4%		

a. Sensitivity and specificity were determined using standard reference samples: Seraseq® gDNA TMB Mix, Seraseq® FFPE BRCA1/2 LGR Reference Material, Seraseq® Breast CNV Mix, Seraseq® Lung & Brain CNV Mix (SeraCare, USA); Oncospan gDNA, BRCA germline I gDNA, Pan-Cancer 6-Fusion Panel, Tru-Q0 DNA Reference Standards (Horizon, USA); EMQN RNA fusion reference samples.
b. Somatic SNVs and INDELs at 1% ≤ VAF <5% were detected with 82% sensitivity and >99% specificity.
c. OPA was benchmarked with SOPHIA DDM HRD Solutions (Sophia Genetics, France).
d. MSI and TMB performance for matched tumor-normal analysis. For FFPE-only testing, accuracy of MSI and TMB analysis was reduced by 5-10%.
e. Tumor tissue of origin was predicted by the proprietary OnCUP machine learning model, using whole mRNA profile of the tumor. The top 2 tissues were reported.



Analytical performance for
liquid biopsy sample

		Minimum tumor fraction	Sensitivity ^f	Specificity ^f	Positivity threshold
Targeted therapy (Plasma)	Somatic variants (at LOD = 0.1%) ^g				
	SNVs		95.6%	>99%	≥2 reads
	INDELs (<20 bp)				
	Fusion (common fusions)	0.1%	90.5%	>99%	≥2 reads at breakpoint
	Amplification	2%	81.3%	>99%	≥2 copy ratio (2.2 copies)
ctDNA-MRD (sample-level)	Tumor-informed mutations + Genome-wide features	0.005%	93.3%	>95%	≥1 positive mutation, or positive GW

f. Sensitivity and specificity were determined using clinical sample and standard reference samples: Seraseq® ctDNA MRD Panel Mix (SeraCare, USA); Non-small cell lung cancer ctDNA panel (Horizon, USA).
g. Somatic SNVs and INDELs at 0.01% ≤ VAF <0.1% were detected with 63.8% sensitivity and >99% specificity.

Clinically Validated Performance of ctDNA-MRD Monitoring

Cancer	Stage	Method	Sensitivity to detect recurrence	Specificity to detect recurrence	Lead time before imaging (median)	Study
Colorectal	I – IV (n=89)	Tumor-informed	>99%	>99%	8.0 Mo. (up to 11.1 Mo.)	HTN et al, ESMO RW 2024 ²
Breast	HR+, HER2+, TNBC (n=168)	Tumor-informed	90.9%	98.8%	9.7 Mo. (up to 13.2 Mo.)	STN et al, NPJ BC 2025 ³
Lung	I – III (n=60)	Tumor-informed	84.6%	97.9%	3.2 Mo. (up to 14.4 Mo.)	VANH et al, JCO OA 2025 ⁴
HCC	Early resectable (n=19)	Tumor-informed	83.3%	92.3%	3.3 Mo. (up to 7.3 Mo.)	VANH et al, JCO OA 2025 ⁴
Gastric	I – III (n=54)	Tumor-informed	75.0%	95.0%	5.0 Mo. (up to 6.1 Mo.)	VANH et al, JCO OA 2025 ⁴

2. HTN et al, Clinical trial and real-world evidence of circulating tumor DNA monitoring to predict recurrence in patients with resected colorectal cancer, ESMO Real-world Data and Digital Oncology, 2024
3. Nguyen, S. T. et al. Personalized mutation tracking in circulating-tumor DNA predicts recurrence in patients with high-risk early breast cancer. Npj Breast Cancer 11, (2025)
4. VANH et al, Real-world utilization and performance of circulating tumor DNA monitoring to predict recurrence in solid tumors, JCO Oncology Advances, 2025

K-4CARE Beyond CGP: Unveiling Details, Unlocking Hope

Details that Can Be Missed by Other CGP Tests

K-4CARE CGTP Clinical Impacts

All Cancers

- **RNA-Based Fusion Detection**
20% enhanced sensitivity for common & rare fusions
- **DNA-Based Fusion Detection**
Optimized for low-quality specimens (e.g., failed RNA-seq)

- **Maximize access to gene fusion-targeted therapies**

Breast & Ovarian Cancer

- **Backbone-Enhanced Design**
Boosts sensitivity detection to detect large indels and genomic rearrangements in BRCA1/2
- **Validated sWGS Workflow**
Assesses whole-genome instability for HRD testing

- **2-3% more patients may benefit from BRCA-targeted therapies⁵⁻⁶**
- **Benefit > 50% of ovarian cancer patients to access PARP inhibitors⁷**

Lung Cancer

- **Integrated DNA-seq & RNA-seq**
Improves sensitivity to detect METex14 skipping variants compared to DNA-seq alone⁸

- **Maximize access to MET-targeted therapies**

Cervical, Head & Neck, Liver, NPC Cancers

- **Oncovirus Profiling**
Detects HPV, HBV & EBV to inform prognosis and monitoring

- **Better inform prognosis, treatment and monitoring plans**

CUP – Cancer of unknown primary

- **DNA-seq:**
Identifies actionable mutations
- **RNA-seq:**
Leverages machine-learning models to predict tumor tissue-of- origin

- **5% of CUP patients can gain access to personalized therapies**

5. Thaddeus Judkins B et al, Clinical significance of large rearrangements in BRCA1 and BRCA2, Cancer, 2012

6. Do-Hoon Kim et al, Identification of large genomic rearrangement of BRCA1/2 in high risk patients in Korea, BMC Medical Genetics, 2017.

7. González-Martin A et al, Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer, N Engl J Med, 20219.

8. Socinski MA et al, MET Exon 14 Skipping Mutations in Non-Small-Cell Lung Cancer: An Overview of Biology, Clinical Outcomes, and Testing Considerations, JCO Precis Oncol, 2021.

For more information or to request
a brochure, please contact us:

✉ info@genesolutions.com
[Contact Us · Gene Solutions Singapore](#)

